

510(k) Summary

Date Prepared:	22 December 2010
Submitter:	Medtronic, Inc. Cardiac Rhythm Disease Management 8200 Coral Sea Street NE Mounds View, MN 55112
Contact:	Yukiko Corson Regulatory Affairs Specialist
Telephone:	(763)526-3409
Fax:	(651)367-0603
E-mail:	yukiko.m.corson@medtronic.com
Proprietary Name:	Reveal XT Insertable Cardiac Monitor, Model 9529 Reveal XT Patient Assistant 9539 Reveal DX Insertable Cardiac Monitor, Model 9528 Reveal DX Patient Assistant 9538
Common Name:	Insertable Cardiac Monitor
Device Classification	Class II, 21 CFR 870.1025, Arrhythmia detector and alarm
Product Code:	DSI

Summary of Substantial Equivalence

The intended use, design, materials and performance of the Reveal XT Model 9529 and Reveal DX Model 9528 Insertable Cardiac Monitors, Reveal XT Patient Assistant 9539 and Reveal DX Patient Assistant 9538 are substantially equivalent to the following predicate devices:

- Medtronic Reveal XT Model 9529 Insertable Cardiac Monitor (ICM) originally cleared via 510(k) reference K071641 and the Reveal DX Model 9528 Insertable Cardiac Monitor originally cleared via 510(k) reference K071655 on November 21, 2007 (including patient assistants). The Reveal XT Model 9529 and Reveal DX Model 9528 enhancements previously cleared via 510(k) reference K082475 on November 7, 2008 (including patient assistants).
- Instromedix King of Hearts Express AF Recorder - K020825, Cleared April 5, 2002

Device Description

The Reveal XT Model 9529 and Reveal DX Model 9528 Insertable Cardiac Monitors (ICM) are designed to automatically record the occurrence of arrhythmias in a patient. Arrhythmia may be classified as atrial tachyarrhythmia/atrial fibrillation (AT/AF), bradyarrhythmia, asystole, or

(fast) ventricular tachyarrhythmia. The Reveal XT ICM provides storage of ECG and Marker Channel during patient-activated and automatically-detected (auto-activated) events. Auto activation may help to detect abnormal heart rhythms in patients who may not activate/trigger the ICM.

The Reveal XT ICM Model 9529 and Reveal DX Model 9528 are small, leadless devices that are typically implanted under the skin, in the chest. Two electrodes on the body of the device continuously monitor the patient's subcutaneous ECG.

The Reveal XT Patient Assistant Model 9539 and the Reveal DX Patient Assistant Model 9538 are hand-held, battery-operated telemetry devices that enable the patient to start recording cardiac information in the Reveal XT and DX ICMs, respectively after experiencing symptoms of a possible cardiac event. The Reveal XT Patient Assistant query function enables the patient to check the status of physician-programmed parameters. A query function enables the patient to check his or her device and receive notification when an arrhythmia has occurred or when the device status has changed.

Indications for Use

The Reveal XT and DX Insertable Cardiac Monitors are implantable patient-activated and automatically-activated monitoring systems that record subcutaneous ECG and are indicated in the following cases:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms such as dizziness, palpitation, syncope and chest pain, that may suggest a cardiac arrhythmia.

The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates one or more of the data management features in the Reveal Insertable Cardiac Monitor:

- To verify whether the implanted device has detected a suspected arrhythmia or device related event. *
- To initiate recording of cardiac event data in the implanted device memory.

*only applicable to the Reveal XT Patient Assistant Model 9539

Technological Characteristics

Intended use, design, materials, performance and technological characteristics are substantially equivalent to the predicate devices referenced.

Summary of Testing

There are no changes to the hardware, materials, processes, packaging, shelf life and sterilization of the Reveal XT and Reveal DX Systems included in this submission. Therefore, electromagnetic compatibility (EMC), electrical safety, mechanical performance, component, biocompatibility, sterilization and packaging testing were not repeated since the 510(k) clearance via K071641, K071655.

K103764
P3/3

Software and system verification testing, system validation testing, electrical design verification testing, human factors testing, and performance validation testing (bench and animal) were performed to demonstrate that the Reveal XT Model 9529 Insertable Cardiac Monitor met established performance criteria and to support equivalency with the reference predicate devices.

The results of the testing indicate that the Reveal XT/DX Insertable Cardiac Monitors, Model 9529 and 9528, Reveal XT/DX Patient Assistants Model 9539 and 9538 perform as intended and are safe for their intended use.

Conclusion

Medtronic considers the Reveal XT and Reveal DX Insertable Cardiac Monitor systems to be substantially equivalent to legally marketed predicate devices through the data and information presented. No safety or effectiveness issues were identified.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Medtronic, Inc.
Cardiac Rhythm Disease Management (CRDM)
c/o Ms. Yukiko Corson
Regulatory Affairs Specialist
Mounds View MN 55112

MAY - 4 2011

Re: K103764

Trade/Device Name: Reveal XT Insertable Cardiac Monitor, Model 9529;
Reveal XT Patient Assistane, Model 9539
Reveal DX Insertable Cardiac Monitor, Model 9528;
Reveal DX Patient Assistane, Model 9538

Regulation Number: 21 CFR 870.1025

Regulation Name: Arrhythmia detector and alarm (including ST-segment
measurement and alarm)

Regulatory Class: Class II (two)

Product Code: DSI

Dated: March 31, 2011

Received: April 1, 2011

Dear Ms. Corson

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



[Handwritten signature of Bram D. Zuckerman, M.D.]

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indication for Use

510(k) Number (if known): K103764

Device Name: Reveal XT Insertable Cardiac Monitor (9529)

Reveal XT Patient Assistant (9539)

Reveal DX Insertable Cardiac Monitor (9528)

Reveal DX Patient Assistant (9538)

Indications for Use: The Reveal XT/DX Insertable Cardiac Monitor is an implantable patient-activated and automatically-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias.
- Patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain, that may suggest a cardiac arrhythmia.

The Reveal XT/DX Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates one or more of the data management features in the Reveal Insertable Cardiac Monitor:

- To verify whether the implanted device has detected a suspected arrhythmia or device related event. *
- To initiate recording of cardiac event data in the implanted device memory.

**only applicable to the Reveal XT Patient Assistant Model 9539*

Prescription Use X AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 807 Subpart C)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103764